

# The Biologics Control Act of 1902 and the Regulation of Biologics: A Brief Reflection

---

William M. Egan, Ph.D.

Deputy Director

Office of Vaccines Research and Review

# The Impact of Vaccines

Disease	Base Morbid.	1998 Morbid.
Diphtheria	175, 885	1
Polio (paralytic)	16, 316	0
Measles	503, 328	89
Rubella (CRS)	823	5
Hib	20, 000	54
Smallpox	48, 164	0

MMWR 48(12), 243-48 (1999)

# The Horse Named Jim

Inoculated

August 10

September 22

Bled

August 24 (10 L)

September 30 (8L)

---

Jim showed signs of tetanus on October 2  
and was killed.

# The Coroner's Verdict

“From this we conclude that the serum of September 30 was issued without having been tested by the proper methods, and that a part of it was filled into bottles bearing the date of August 24, or was furnished with labels having previously been stamped with this date.”

“ ... the serum drawn on August 24 was free of tetanus, but that the serum of September 30 was drawn during the period of incubation, and had it been tested upon animals it must necessarily have revealed its toxic properties.”

<i><b>Product</b></i>	<i><b>Incident</b></i>	<i><b>Cause(s)</b></i>
Smallpox	Transmission of disease (e.g., hepB)	Lack of knowledge
TAM	Free toxin (produced after freezing)  Free toxin filled in vials	Lack of knowledge  Lack of foresight, negligence
BCG	Virulent tuberculosis strain admixed BCG	Lack of foresight, negligence
IPV	Live virus remaining in vaccine	Lack of foresight

Sir Graham S. Wilson, *The Hazards of Immunization*, The Athlone Press, London, 1967

# A Research Agenda

- Vaccine Characterization
  - Physical
  - Biological
- Adventitious Agents
  - Detection (esp. generic methods)
- Adverse Events
  - Vaccine inherent
  - Host factors
- Mechanism of protection and correlates of protection

**It is for us, and for those who come after us, to see that the sword which vaccines and antisera have put into our hands is never allowed to tarnish through over-confidence, negligence, carelessness, or want of foresight on our part.**

Sir Graham S. Wilson, *The Hazards of Immunization*, The Athlone Press, London, 1967